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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Villoo Morawala Patell

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT

PAPER NUMBER

1638

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,887	Applicant(s) PATELL, VILLOO MORAWALA	
	Examiner Cynthia Collins	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on July 27, 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-20,23-25 and 29-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-20,23-25 and 29-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's submission filed on July 27, 2009 has been entered.

Claims 1-16, 21-22 and 26-28 are cancelled.

Claims 29-33 are new.

Claims 17 and 23-24 are currently amended.

Claims 17-20, 23-25 and 29-33 are pending and are examined on merits in this Office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Specification

The amendment filed July 27, 2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: that the increased MnSOD activity is increased “in the presence of increased methylviologen concentration”. Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 24 remains rejected, and claim 33 is rejected, under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's assertion that a declaration by the Applicant satisfying the deposit requirements under 37 CFR §§ 1.803-1.808 will be submitted is acknowledged.

Claim Rejections - 35 USC § 103

Claims 17-20, 23 and 25 remain rejected, and claims 29-32 are rejected, under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al. (Salt tolerance of transgenic rice overexpressing yeast mitochondrial Mn-SOD in chloroplasts. *Plant Science*. 1999. 148: 131-138) in view of Bowler et al. (European Patent Publication No. EP 0359617A2, Published March 21, 1990, Applicant's IDS), Nayak et al. (Transgenic elite indica rice plants expressing CryIAc delta-endotoxin of *Bacillus thuringiensis* are resistant against yellow stem borer (*Scirpophaga incertulas*). *Proc Natl Acad Sci U S A*. 1997 Mar 18;94(6):2111-6), Verdaguer et al. (Isolation and expression in transgenic tobacco and rice plants, of the cassava vein mosaic virus (CVMV) promoter. *Plant Mol Biol*. 1996 Sep;31(6):1129-39), and Davuluri et al. (Oxidative stress management-targeting MnSOD to the chloroplast. Meeting Abstract. *Plant Biology (Rockville)*, (1999) Vol. 1999, pp. 103. print. Meeting Info.: Annual Meeting of the American Society of Plant Physiologists. Baltimore, Maryland, USA. July 24-28, 1999. American Society of Plant Physiologists (ASPP)).

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Applicants submit that the references do not provide any reasonable basis to conclude that a stable transformation of indica rice with N. *Plumbaginifolia* L. MnSOD as recited in claim 17 can be achieved, because significant variation can be expected where the host genomes are different, especially if the plants are from or related to different species. Applicants also point out that indica and japonica rice are clearly distinguishable based on physiological and morphological traits, and maintain that given the differences between indica and japonica rice, there is no reasonable basis from Tanaka to conclude that Tanaka's studies using a different transgene and host genome would lead to a predictable application in Nayak's indica rice variety. Applicants additionally point out that Tanaka indicates that stable transformation of crop plants using the SOD is unpredictable, especially if different genomes are used (page 136). Applicants further maintain out that Nayak's experiments substantiate the general understanding that there are multiple sources of unintended changes in transgenic plants, including the transgene itself, and that the teachings in the references substantiate the general understanding in the art of plant transformation that application of transformation protocols which minimize variability among transgenic plants is complicated and remains unpredictable by widely occurring species or variety specificity with respect to transformation procedures.

With respect to Tanaka, the Examiner maintains that Tanaka does not indicate at page 136 that stable transformation of crop plants using the SOD is unpredictable; Tanaka indicates at page 136 that the generation of transgenic plants by several other groups that overexpressed SODs in order to enhance tolerance to oxidative stress such as MV, chilling, ozone and water deficit, has been successful to various degrees. Accordingly, it is reasonable to conclude from

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Tanaka that one skilled in the art would have a reasonable expectation of success with respect to the expression of MnSOD in indica rice.

With respect to Nayak, the Examiner maintains that it is reasonable to conclude from Nayak that one skilled in the art would have a reasonable expectation of success with respect to the expression of MnSOD in indica rice, since Nayak successfully produced transgenic indica rice plants that express a CryI Δ C delta-endotoxin coding sequence. That it was known in the art that the CryI Δ C genes used by Nayak would require substantial modification in order to be successfully expressed in transgenic plants is inapposite to the outstanding rejection and claims, since the rejected claims require an MnSOD gene, and since no such substantial gene modification appears to be required to express MnSOD genes in transgenic plants.

With respect to the remaining references of Bowler, Verdaguer, and Davuluri, the Examiner maintains that it is reasonable to conclude from Bowler, Verdaguer, and Davuluri that one skilled in the art would have a reasonable expectation of success with respect to the expression of MnSOD in indica rice, since each of Bowler, Verdaguer, and Davuluri were successful in their application of their respective transformation protocols.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cynthia Collins/
Primary Examiner, Art Unit 1638

CC